Claims 1, 3-8, and 11-12 were rejected under 35 USC 102(e) based on US patent 6,264,695 (Stoy 2001), which relates to a small and specialized type of spinal cartilage, called "nucleus pulposus" tissue.

As originally submitted, claims 1-12 initially referred to any type of "damaged cartilage". However, as set forth in numerous locations throughout the text (including paragraphs 18-26 in the published version), the intent of the inventor, attorney, and application were to exclude spinal cartilage. To accomplish that goal, all of claims 1-12 have been amended, by limiting the only independent claim in that set (claim 1) to "damaged cartilage in a joint that is lubricated by synovial fluid".

That phrase requires some explanation, and it is accompanied by a clarifying amendment to paragraph 21 (as numbered in the published version) of the specification.

As originally described in paragraph 21, the type of cartilage found in spinal discs is referred to as *fibro*-cartilage, by the large majority of recognized and respected reference works in this field. Upon learning of Stoy's statement in column 14, lines 6-7 (which was pointed out by the Examiner), referring to "the hyaline cartilage of vertebral endplates", the Applicant and undersigned attorney initially thought it was simply wrong, and was an inadvertent error made by Stoy, who is a chemist rather than a physician or physiologist.

However, upon searching a number of reference works, the Applicant discovered that a small minority of such works do indeed refer to hyaline cartilage being on at least some vertebral bone surfaces. This may refer only to such bone surfaces in immature animals, but the references are not completely clear.

Rather than debating whether those reference works are correct or mistaken, on that particular point, the Applicant has attempted to address and clarify the matter by pointing out, in the enclosed amendment to the specification, that most reference works call it fibrocartilage, but some references refer to it as hyaline cartilage. That is a more accurate, reliable, and helpful observation than the original statement in the specification, and the examiner's role and assistance in bringing the facts to light is sincerely appreciated.

Furthermore, it was also realized that the term "articulating" is not always used consistently in the art. Some publications effectively limit that term to joints that involve sliding motions between cartilage surfaces that rub against each other, which excludes the spine; however, other publications apparently use "articulating" in ways that would include the type of non-sliding flexing motions and connections in the spine.

Therefore, it was realized that a useful and reliable way to limit and clarify the claim coverage so that it clearly and undeniably excludes spinal joints and vertebral bones (as described and intended in the original application) is by referring to "joints that are lubricated by synovial fluid". This is believed to cleanly and clearly exclude the spine, and the joints between vertebral bones, since those joints are lubricated by a completely different type of fluid (i.e., cerebrospinal fluid, or CSF).

Furthermore, that amendment is entirely consistent with other explicit limits in the claims, such as the phrase in Claim 1 which refers to a "lubricious surface which has a negative electrical charge density that promotes lubricious interactions with mammalian synovial fluid". That does not and cannot occur in spinal joints, since spinal joints do not contain synovial fluid.

One other comment on page 2 of the Office Action also needs attention. The Office Action stated that Stoy's hydrogel device could be "anchored, by friction fit between two bones". That statement is not consistent with the Applicant's use of the word "anchoring".

As used in the current application, and as recognized and understood in common usage by orthopedic surgeons, an implantable device is surgically "anchored" only if it is securely and firmly attached (such as by sutures, staples, pins, or tissue ingrowth) to a surface of a specific body part (which can be a bone, or soft tissue adjacent to a joint that is being repaired, such as the tendons and ligaments that form the capsule that encloses a knee joint). A slippery device that is held within a limited space might be regarded as being trapped, constrained, secured, or similar terms; however, it cannot be referred to as being "anchored", as used in the current application, unless it is directly affixed to one of the surfaces it contacts.

This issue also points out and highlights a crucial difference between the art of Stoy '695, and the current invention. The cylinder disclosed in Stoy '695 does not need to be securely anchored to any type of tissue surface; instead, it works best when simply trapped within a surrounding sleeve, in a manner that allows it to slide and move within that sleeve.

By contrast, when a cartilage-replacing implant is used to replace hyaline or meniscal cartilage in a knee, hip, shoulder, or similar joint, it is absolutely crucial that adequate means must be provided, for firmly and securely anchoring the implant to at least one type of tissue (such as a hard bone surface, the inside of a knee capsule, etc.). Please note also that any reference to "adequate means" for anchoring such an implant requires that the anchoring means must be able to last and endure, not just for years, but for decades, despite being subjected to repetitive compressive, shearing, torsional, and other stresses.

Stoy is a chemist, rather than a surgeon. He did not even attempt to address or face up to the crucial need for providing an adequate and long-lasting means for anchoring his proposed implant materials, to surrounding tissues. In his spinal repair patent, US 6,264,695, he apparently and presumably did not need to do so, since he limited that invention to a cylinder that could simply be emplaced, without any anchoring, inside a sleeve-type enclosure, where it would be allowed to move and slide. Yet even in his subsequent work, described in his published application 2004/0070107 (discussed in more detail below), which purportedly claims to provide better chemical mixtures for use in hydrogels that can be implanted in knees, hips, or shoulders, he still did not face up to, or even attempt to address, the need to provide strong, secure, and durable anchoring of those chemical devices, to the types of tissues that will need to hold and support those implants.

That is a huge and crucial difference between Stoy's art, and the current invention, and those two different lines of work can and should work together, in highly useful ways. Stoy is a chemist, and he is making very useful advances in creating better chemistry, for creating smooth, slippery, and durable hydrogel compounds. However, he does not have the set of skills that are needed, to figure out how to configure his hydrogel materials into devices that can be properly and securely anchored to tissues, in load-bearing joints.

By contrast, the inventor of the current application, Kevin Mansmann, is an orthopedic surgeon, rather than a chemist. He is crucially concerned with, and intently focused upon, developing methods, devices, and tools that are specifically designed to enable strong and secure anchoring of flexible implants (such as hydrogel polymers, made by processes developed by chemists such as Stoy) onto the bony or soft tissues that will need to support those implants, using arthroscopic methods to minimize damage to the surrounding tissues and blood vessels.

Instead of regarding their work as conflicting or competing against each other, the Examiner and the Patent Office should recognize that their efforts are entirely complementary, and mutually supportive of each other. Both types of efforts are essential in creating, testing, proving, and commercializing better ways to repair damaged joints, in patients who truly need help. Accordingly, both lines of work are fully deserving of good and valid patent protection.

NOVELTY REJECTION BASED ON US 4,836,884 (McAUSLAN)

Claims 1, 8-9, 19, and 25-26 were rejected under 35 USC 102(b), based on US 4,836,884 (McAuslan). That rejection indicates a misreading of McAuslan '884. That patent disclosed "etching" of hydrogel surfaces, not to render them smooth and lubricious, but to encourage cells to grow into, and onto, the etched surfaces.

However, that type of cell growth, on smooth surfaces that are designed to provide sliding cartilage surfaces in an articulating joint, would be exactly the *opposite* of what is useful and desirable, in the current invention.

Cell growth on the ***back*** side (i.e., the anchoring side) of an implant is fine, and indeed desirable, to provide stronger anchoring. However, stronger anchoring is exactly the opposite of what is wanted, for the ***slippery*** surface of a cartilage-replacing implant. Any growth of cells on that sliding surface would foul and clutter the smooth surface, and would lead to crushing of the cells, and the creation of debris that could and likely would abrade and harm the smooth sliding surfaces of the cartilage.

The types of acids taught by McAuslan will indeed "etch" the surfaces of the hydrogels he is treating, as McAuslan states in numerous locations in his text (including the Abstract, the Summary of Invention, etc.). In his usage, "etching" refers to deliberately creating a type of surface ***roughness***, rather than increased smoothness. Increased roughness can be valuable for promoting cell growth on a polymer surface, since it gives so-called "anchorage-dependent cells" better opportunities and more locations to "nestle" and "snuggle" down into the microscopic crevices, gaps, and other surface deficits created by the etching process.

Although McAuslan fails to explain it adequately, mammalian cells that are reproduced by cell culture are divided into two main categories, referred to as "suspension cells" and "anchorage-dependent cells". Many types of blood cells (and a few other types of specialized cells) can reproduce while fully suspended in suitable nutrient liquids, since those cells do not need to attach themselves to a surface. However, most cell types that form connective tissues in mammals can reproduce, both in the body and in cell-culture conditions, only after they have become affixed to a solid surface. Those types of cells are called "anchorage-dependent cells", and they are the types of cells McAuslan was working with.

In order to provide anchored cells with both (i) an adequate supply of nutrients, and (ii) adequate removal of waste products and metabolites, stirring, rocking, or other controllable motion of the nutrient liquid mixture that bathes the cells is almost always required, when anchorage-dependent cells are being grown in cell culture. However, any such motion by the surrounding liquid will pose a risk of disrupting and breaking the relatively fragile attachments that anchorage-dependent cells use, to anchor themselves to solid surfaces. Therefore, it has been found that both (i) manipulation of electrical charge densities, and (ii) the creation of etched and microscopically-irregular surfaces, having crevices and other gaps that are roughly comparable to the diameters of the cells, can be helpful and useful, in helping the cells gain "footholds" on the surfaces they are attempting to attach to.

However, that type of etching process, which deliberately creates tiny crevices, gaps, and other surface irregularities that will help support and promote cell growth, is exactly the *opposite* of what is wanted, on the smooth articulating surface of a cartilage-replacing implant. Cell-growing surfaces are good and useful for *anchoring* surfaces, on the "back" sides of cartilage-replacing implants, but they are unwanted and would be highly adverse, if present on the smooth and slippery *articulating* surfaces of those same implants.

Accordingly, the McAuslan rejection should be withdrawn.

OBVIOUSNESS REJECTIONS BASED ON US 6,264,695 (STOY)

Claim 2 was rejected under 35 USC 103(a), based on Stoy '695, which relates to spinal repair, as discussed above. Since Claim 2 depends on claim 1, which is amended herein to completely avoid any coverage of any type of spinal repair, this rejection should be withdrawn for the same reasons described above.

Claims 9, 13-23, and 25-26 were also rejected under 35 USC 103(a), based on US patent 6,264,695 (Stoy 2001) combined with Stoy's application 2004/0070107.

That obviousness rejection should be withdrawn, since Stoy's art -- even if combined in the manner suggested by the Examiner -- completely fails to teach, suggest, or face up to the crucially important set of challenges that will require an implant, in a synovial joint, to be securely and durably anchored to a bone or soft tissue.

As mentioned above, Stoy '695 sidestepped that issue, while describing a spinal implant, by asserting (in effect) that the spinal implant would merely be emplaced within a sleeve-type enclosure, where it would be able to move and slide.

However, in Stoy's '107 application, which purportedly described implants for replacing cartilage in knees, hips, shoulders, and similar joints lubricated by synovial fluid, that approach simply cannot, and will not, work. Any such implant absolutely ***must*** be strongly, securely, and durable anchored to some type of supporting tissue.

And yet, Stoy's '107 application completely and totally fails to teach or even suggest how that can be done. Instead, it merely described a certain line of chemistry that can be used to create good hydrogel materials, which can be molded or cast into various shapes. That is good, useful, and even essential work, but it is not sufficient to teach how to actually repair damaged joints, using flexible implants that can be inserted and anchored via small incisions, using arthroscopic tools and methods.

Accordingly, the current inventor, an orthopedic surgeon, has focused intently on the challenges and demands of: (i) inserting flexible implants into joints, via arthroscopic insertion tubes, and (ii) providing suitable means, incorporated as components of the implants, for strongly, securely, and durably anchoring those implants, to supporting bony or soft tissues. His efforts have created extraordinarily promising advances, which are different from -- but complementary to -- the chemical work being done by Stoy.

Crucial aspects of Dr. Mansmann's advances are explicitly set forth in several claim limitations, which appear in each independent claim. For example, Claim 1 explicitly requires "a fibrous matrix that extends through at least a portion of the hydrogel material and reinforces the hydrogel material". Claim 13 requires both "a polymeric hydrogel component, at least a portion of which is reinforced by a flexible fibrous matrix", and, "at least one anchoring component that is designed to allow anchoring of the implant to soft tissue." Claim 19 requires both, "a polymeric hydrogel component, at least a portion of which is reinforced by a flexible fibrous matrix", and, "at least one anchoring surface designed to promote ingrowth of osseous tissue following surgical implantation." Claim 25 requires, "a fibrous reinforcing matrix that extends through at least a portion of the hydrogel material".

Those claim limitations are stated in relatively brief phrases; however, those phrases are supported by drawings and descriptions of how such components can actually be provided, in implants that can be inserted, and then securely and durably anchored, using arthroscopic tools and methods. Those teachings are absolutely essential in supporting and explaining the claims, and in enabling an actual implant to function effectively. And yet, those types of teachings are completely and totally absent, in Stoy's work.

Stoy and his attorney both had to realize, at some level of awareness and planning, that some type of anchoring of Stoy's implants, to bony or soft tissue, would be absolutely essential, when replacing cartilage in a joint such as a knee, hip, or shoulder. That type of requirement, in this type of surgery, is so obvious and apparent that no one who works in this field can claim or pretend otherwise. And yet, nowhere in Stoy's application did they even attempt to address, explain, or solve that absolutely crucial and central set of challenges.

These statements are made with the full realization that surfaces 23 and 37, shown by Stoy in FIGS. 2 and 3 and described in their Example 4 (paragraph 51), are said to be "microporous", and are positioned in locations that presumably are intended to promote tissue ingrowth. However, those statements and appearances do not solve the problems of actually creating secure anchoring, at all. Tissue ingrowth does not even begin, on any substantial level, for weeks, and it does not approach a level of genuine and reliable strength for months; and, during those extended delays, even small and minor motions and jostling can tear apart and completely destroy any and all tissue ingrowth that has occurred up until that moment in time, forcing the entire process to start over (indeed, it cannot even get a fresh start, since from that moment on, the micropores likely will be filled with dead and dying cells and other matter that will hinder, rather than promote, a new start). How can a cone-shaped device, with nothing more to hold it in position or prevent rotation, have any realistic expectation of trying to overcome that hurdle? The answer is, it can't.

Beyond that, no one knows what will actually happen, if cells in living *in vivo* tissue begin trying to grow into the types of synthetic hydrogels they are actually creating. How will sufficient quantities of nutrients reach those cells? Will their metabolites and waste products be removed adequately, or will they accumulate to toxic levels inside the polymer matrix? To put it simply, using a flexible polymeric hydrogel as an anchoring layer, to promote cell ingrowth, is not a good choice, and not a good design. There are much better types of anchoring materials that have shown good utility and reliability, in actual surgical use, over years and even decades of practice. However, Stoy and his attorney said nothing about any of those types of materials, or about how their polymers could be securely bonded to those types of materials.

Instead, Stoy and his attorney chose to simply remain absolutely silent, on the issue of anchoring. They did not even try to assert that their microporous surfaces 23 and 37 could or would support or promote tissue ingrowth. They likely realized that anything they might have written about anchoring or tissue ingrowth -- without having worked for a long time on ways to address and overcome the very real obstacles it poses -- likely would have been unreliable, or even false and misleading. Since their claims were limited to chemical processing methods, and to artificial joint ***components*** made by those methods (rather than to complete and functional implants that *include* those types of hydrogel components), they took the best and most logical approach they could, based on what they knew at that time. They simply remained silent, about a set of problems they could not answer.

Their complete and total silence, on a crucial issue that sits at the very heart of surgically-implantable devices, does not render the current invention obvious. Instead, it provides powerful and even compelling evidence that other people working in this field of art simply could not provide the types of answers and solutions that were subsequently discovered, and disclosed, by an orthopedic surgeon who actually does this kind of work, and who must and solve face these kinds of problems, instead of simply ducking them.

Accordingly, the invention is not obvious, and the rejection should be withdrawn.

OBVIOUSNESS REJECTION BASED ON STOY '695 AND OKA '478

Claims 1, 8-10, and 25-27 were rejected under 35 USC 103(a), based on a combination of Stoy '695 (discussed above) with US 5,314,478 (Oka et al 1994).

As apparently recognized by the Examiner, what appears to be a "fiber matrix", shown by Oka's callout number C1 in FIG. 1, is actually a very hard and non-yielding metal alloy or porous ceramic, as clearly set forth in locations such as column 5, lines 37 ("porous alumina ceramics C1") and 45 ("metallic or ceramic porous bodies"). These are indeed conventionally used, in numerous types of surgical implants that are anchored directly to hard bone surfaces, which is the only disclosed method for anchoring Oka's implants.

Unfortunately, Oka's implant designs never succeeded, and one of the reasons is that hydrogels will not survive for long, if subjected to repeated stresses and loadings that press the flexible hydrogel material into hard and abrasive metallic or ceramic edges and surfaces. Under such conditions, the metal or ceramic edges of the gel reinforcing materials will begin acting as cutting or abrading surfaces, which will damage the hydrogel.

This is clearly and explicitly set forth in paragraphs 0052 through 0054 of the current application, which includes passages such as, "[0052] Any use herein of terms such as matrix, mesh, fiber, fibrous, or strand, in the discussion or claims below, is intended to refer to a matrix that is made of *fibers that will readily flex and bend, in a manner comparable to thread* used for stitching, or strands woven into fabric . . . "fiber mesh" structures made of hardened metal alloys, for promoting bony tissue ingrowth, are totally different from fibrous matrices made of flexible thread-like strands, for reinforcing flexible hydrogels as disclosed herein. As used herein, terms such as "fibrous matrix" refer to three-dimensional fibrous structures made of *fibers that are readily and inherently flexible, at body temperatures.*"

Accordingly, the current invention is very different from the Oka class of proposed implants (which did not succeed), and this rejection should be withdrawn.

If the Examiner wishes, we can discuss an amendment to insert the word "flexible" before each occurrence of the phrase "fibrous matrix". However, that should not be necessary, since (i) conditions of flexibility might need to be spelled out somehow, since nearly anything that is not brittle will bend, if stressed under sufficient force; (ii) all occurrences of "fibrous matrix" in the claims are already subject to the teachings and definitions set forth in paragraphs 0052-0054; and, (iii) the title even refers to "*flexible* matrix reinforcement".

CONCLUSION

In view of the foregoing remarks and enclosed amendments, it is believed that the claims, as amended, are now in condition for allowance. If any questions remain, please contact the undersigned attorney at 314-822-8558.

Respectfully submitted,

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